UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

	:	ECF Case
IN RE GPC BIOTECH AG SECURITIES	:	
LITIGATION	:	07-CV-06728 (DC)
	:	

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' CONSOLIDATED CLASS ACTION COMPLAINT

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The essence of Plaintiffs' case, as stated in their Complaint, is that the FDA affirmatively told GPC early in the development cycle that the progression-free survival ("PFS") endpoint could not serve as a basis for accelerated approval of satraplatin. Cmp. ¶¶ 15, 101. In its Motion to Dismiss, GPC established that Plaintiffs' failure to plead even the most basic details supporting this – the "who, what, where, when, or how" – rendered the Complaint legally insufficient to support a claim for securities fraud.

Plaintiffs implicitly surrender to this argument by jettisoning that theory of their case and rummaging about for an alternative theory they hope will fare better. However, with the lack of any particularity in the Complaint having been exposed, Plaintiffs now can only theorize that "[t]he FDA clearly communicated *something* to GPC during the development phase of the clinical trial."[1] They then go on to speculate about what that "something" *could* have been. The PSLRA, however, requires particularized allegations of fraud. Speculation will not suffice.

Ultimately, Plaintiffs appear to settle on two newly-minted (and mutually exclusive) fallback theories. Plaintiffs now contend that GPC's representations that the FDA had agreed to GPC's use of PFS as an endpoint were fraudulent because either: (a) the FDA, having never encountered PFS before, could not possibly have agreed to GPC's use of it; or (b) even if the FDA did agree to accept PFS as an endpoint, GPC's disclosure of that agreement was materially misleading because it did not also disclose that the FDA was inexperienced with the specific

[1] Memorandum of Law in Opposition to Defendants' Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint ("Plaintiffs' Opposition" or "Pltfs. Opp.") at 3 (emphasis added). The Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint is referred to herein as "Defs. Mem."

criteria GPC used to measure satraplatin's effect on PFS. As shown below, Plaintiffs' new theories are just as baseless as the old one.

B. Plaintiffs' New Fallback Theories Deliberately Conflate Two Important But Fundamentally Different Issues Raised in the FDA Review Process

Plaintiffs' retooled theories, like their abandoned one, rest on a clear distortion of the following passage, which appears in the July 20, 2007 FDA Briefing Document (and is repeated in the July 24, 2007 ODAC Meeting Minutes):

> PFS is defined [for purposes of the SPARC trial] as a composite endpoint, consisting of radiographic progression, symptomatic progression (pain, analgesics, ECOG performance status, weight loss and other clinical events related to prostate cancer) and skeletal related events. ***The FDA has no prior experience with this endpoint***. This was clearly communicated to the Applicant during the development phase.

FDA Briefing Document at 3, Affidavit of Bernard J. Garbutt III ("Garbutt Aff."), Exh. 8 (emphasis added). As explained in Defendants' opening memorandum, the inexperience to which the FDA was alluding was inexperience with the particular composite definition of PFS that GPC used to measure satraplatin's effect on PFS, not inexperience with PFS *generally*.

Nevertheless, Plaintiffs continue to insist that the quoted language proves that the FDA had never before encountered a PFS endpoint. *See, e.g.*, Pltfs. Opp. at 3. But Plaintiffs *must* know their position is almost laughably false. Defendants' opening memorandum cited a number of cases describing drugs approved by the FDA based on PFS endpoints, as well as analyst reports cited in the Complaint stating explicitly that the FDA has accepted PFS as an endpoint for other cancer drugs. Defs. Mem. at 15, n. 17. In fact, the FDA has issued a Guidance Document describing its extensive experience with PFS and its well-developed thinking about the appropriate role of PFS as a measure of the efficacy of cancer drugs.[2]

[2] The FDA guidance document, which was issued in May 2007, is entitled "Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics" ("Guidance Document"). It was issued in

Unchastened by the facts, Plaintiffs cling stubbornly to their assertion that the FDA had no prior experience with PFS as an endpoint and argue that, having never before encountered PFS, the FDA could not have affirmatively agreed to its use, as GPC represented to investors. Pltfs. Opp. at 2-3, 11-12. Taking this position requires Plaintiffs to do more than just ignore the FDA's extensive track record in approving cancer drugs based on PFS trial results. It also requires Plaintiffs to deliberately conflate two fundamentally different questions.

The first question is: what endpoint will the FDA accept as an appropriate basis for approval? A trial's endpoint is the therapeutic benefit of the drug (the positive effect on a patient's well-being) that the trial is intended to investigate.[3] An FDA agreement to the use of a particular endpoint means only that the FDA agrees that the therapeutic benefit it represents – *if proven* – could merit approval of the drug. The second question is: do the clinical trial results ultimately presented to the FDA prove to its satisfaction that the endpoint has in fact been achieved – *i.e.*, that the drug actually has the clinical benefit in question? *See, e.g.*, Draft Guidance Document, Supp. Garbutt Aff., Exh. 11. One cannot fully appreciate how baseless Plaintiffs' case is without a clear understanding of the critically important difference between these two issues.

1. Issue 1: What Endpoint – *i.e.*, Therapeutic Benefit of the Drug – Would Warrant FDA Approval?

The first approvability question relevant here is whether the endpoint used in a clinical trial to measure the efficacy of a drug is one the FDA regards as an appropriate basis for

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draft in April 2005 ("Draft Guidance Document"). The Draft Guidance Document is submitted as Exhibit 11 to the Supplemental Affidavit of Bernard J. Garbutt III, sworn to August 8, 2008 ("Supp. Garbutt Aff."), and the Guidance Document issued in May 2007 is submitted as Supp. Garbutt, Aff. Exh. 12. The Court may properly take judicial notice of these documents. *See* Supp. Garbutt Aff. ¶¶ 2-4.

[3] Although the endpoints discussed here are efficacy endpoints (which assess the effectiveness of a drug), the FDA also considers other endpoints in the review process, such as endpoints assessing the safety of a drug. *See, e.g.*, Draft Guidance Document, Supp. Garbutt Aff., Exh. 11.

approval of the drug. The answer turns on whether the effect that the endpoint represents – that is, the benefit the drug is intended to provide to patients – is one the FDA regards as "clinically meaningful" or "clinically relevant." *See, e.g., id*. at 2. Not all effects are. For example, a drug shown to be highly effective at improving a cancer patient's skin color would be of little value to the patient, especially when weighed against its risks. Consequently, an endpoint that measures skin color would be unacceptable to the FDA. In contrast, if the effect the endpoint is intended to measure has substantial clinical or "real world" value, *e.g.*, it increases the likelihood of survival, slows progression of the disease, and/or alleviates serious symptoms, achieving that endpoint is far more likely to earn FDA approval. *See, e.g., id*. at 3.

In the case of oncology drugs, an endpoint commonly used as a basis for FDA approval is "overall survival." *See id.* at 5-6. A clinical trial with this endpoint seeks to answer the question: does the drug increase the likelihood the patient will survive for a specified period of time? *Id.* A second efficacy endpoint also frequently used for oncology drugs is "PFS."[4] A trial with this endpoint seeks to answer a different question: does the drug increase the probability that a person will remain alive without the disease getting worse? *See id*. at 8-11.

2. Issue 2: How Does the Trial Protocol Measure Whether the Drug Is Having the Identified Effect (*i.e.*, Achieving the Trial's Endpoint)?

FDA acceptance of a study's endpoint signifies only that the agency regards that endpoint as one that represents a clinically meaningful benefit to patients and thus could warrant FDA approval. *See, e.g., id*. at 6, 9. It does not constitute an agreement that the study results, or the method used to generate them, will be accepted by the FDA as proof of a successful outcome.

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[4] The "progression-free survival" endpoint has replaced a closely related and once commonly used endpoint known as "time to progression" or "TTP." *See* Draft Guidance Document at 9, Garbutt Aff., Exh. 11. Some of GPC's earlier discussions of the SPARC trial referred to the progression endpoint as TTP. Plaintiffs state in their opposition memorandum that "'[t]ime to disease progression' is another term for progression-free survival (PFS)." Pltfs. Opp. at 5.

See, e.g., id. at 13, 16, 17. Consequently, before approving a drug based on test results showing that the endpoint has been achieved, the FDA must answer a second question: are those results reliable and persuasive evidence that the drug actually works?

To answer this question, the FDA must scrutinize the soundness and integrity of the design and execution of the study (the trial protocol). More relevant here, the FDA must, as part of that process, evaluate the reliability of the particular methodology and criteria used to assess whether the drug is having the desired effect in any given patient. For some endpoints, those criteria are comparatively straightforward, overall survival being one example (death vs. survival is a binary proposition).

That is not true with PFS for several reasons. First, the means by which the progression of a disease will be measured depends upon a number of factors, not the least of which is the particular disease at issue. *See, e.g., id.* at 5, 6, 9. Because the detectible manifestations of progression vary from one disease to another, the means of measuring it must as well. *See, e.g., id*. at 5, 10. Moreover, measuring disease progression is an inexact science; evidence of manifestation can be ambiguous and may require judgments that are partially subjective.

For these reasons, the FDA acknowledges that there is no off-the-shelf, ready-made method for evaluating whether a drug intended to slow progression of a disease is effective in doing so. In its guidance document, the FDA observed that, contrary to Plaintiffs' assumption, PFS is not a one-size-fits-all concept and "[t]he role of PFS as an endpoint to support licensing approval varies in different cancer settings." *Id.* at 9. It also emphasized that "[t]here are no standard regulatory criteria for defining progression," and the "definition [of PFS] varies" among studies. *Id.* at 9, 10. Instead, the FDA must assess the adequacy of the criteria used to measure a drug's effect on PFS on a case-by-case basis. To facilitate that assessment, the FDA requires

that the specific PFS definition to be used in the trial be "detailed in the protocol and statistical analysis plan." *Id.* at 10.

3. Application to the SPARC Trial: *What* Benefit, Or Endpoint, the Trial Was Intended to Assess (Satraplatin's Effect on PFS) vs. *How* the SPARC Trial Sought to Demonstrate that Benefit (GPC's Criteria for Measuring Satraplatin's Effect on PFS)

Early in the satraplatin development cycle, the FDA addressed the first of the two issues discussed above – *i.e.*, the question of what clinical benefit, if proven, would merit accelerated approval of satraplatin – by agreeing that progression-free survival (PFS) in prostate cancer patients is a clinically meaningful benefit and was, therefore, an appropriate endpoint for the SPARC trial. GPC disclosed this agreement in its SEC filings. Cmp. ¶¶ 72, 95. GPC also disclosed that, in considering GPC's application for accelerated approval, the FDA would review not only the progression-free survival data, but the available overall survival data as well. 2006 20-F at 47, Supp. Garbutt Aff., Exh. 14.

As should be obvious from the foregoing discussion of the nature of FDA review, in representing that the FDA had agreed to the use of the PFS endpoint, GPC was simply explaining that the FDA had agreed that a clearly demonstrated effect on the progression-free survival of HRPC patients could lead to accelerated approval of satraplatin. GPC was not addressing the second and entirely different issue of whether the FDA would ultimately agree that the actual results of the SPARC trial, including the criteria it used to measure progression, were sufficiently compelling to warrant approval.[5]

To address the second issue – the means by which GPC would measure satraplatin's efficacy in prolonging progression-free survival – the SPARC trial's protocol detailed the criteria

[5] Indeed, no investor could reasonably have believed GPC meant the latter because, at the time GPC disclosed the FDA's agreement on the PFS endpoint, it had not yet submitted the SPARC trial results for FDA review. *See* Cmp. ¶73 (2005 20F issued in April 2006); *id.* ¶85 (GPC announced SPARC results submitted to FDA in February 2007).

that GPC believed would provide an accurate measurement of satraplatin's effectiveness in improving PFS. FDA Briefing Document, Garbutt Aff., Exh. 8, at 3, 8-10. Rather than examine just one recognized indicator of the progression of HRPC, the SPARC protocol used a composite definition that measured satraplatin's effect on PFS using several recognized indicia that a patient's HRPC is progressing. *Id.* These included "radiographic progression [based on bone scans], symptomatic progression (pain, analgesics, ECOG performance status, weight loss and other clinical events related to prostate cancer) and skeletal related events." *Id.* at 3. As one analyst noted, "[a]lthough the composite endpoint [PFS] in the SPARC trial has not been used previously in registration trials, all of the [individual endpoints that were constituents of GPC's composite endpoint] each have been used in previous registration studies." Deutsche Bank Analyst Report dated July 22, 2007 at 4, Garbutt Aff., Exh. 7; DZ Bank AG Analyst Report dated August 3, 2007 at 2, Garbutt Aff., Exh. 10.

Although unique to the SPARC trial, this composite PFS definition was regarded by some as an improvement over previously-used methods. According to an analyst report cited in the Complaint, for example, a leading expert opined "that the design of the PFS endpoint [in the SPARC trial], being a composite of tumor and pain progression, as well as the conduct of centralized review, are rigorous and set the standard for prostate cancer trials in the future." Pacific Growth Equities Analyst Report, dated February 26, 2007 at 3, Garbutt Aff., Exh. 5.

It is clear that the FDA's expression of unfamiliarity in the 2007 FDA Briefing Document and the ODAC Meeting Minutes related to a lack of experience with the specific composite PFS definition that GPC used in its SPARC trial, not to the use of PFS as an endpoint in the SPARC trial generally. The concerns noted in the agency documents related to the question of whether the results of the SPARC study were persuasive evidence of satraplatin's true effect on PFS, not

whether the PFS endpoint itself was an appropriate one.[6] This shows that, far from rejecting PFS as an endpoint, the FDA was concerned only that the evidence was too inconclusive to establish that the endpoint had actually been achieved. This also shows that a core premise of Plaintiffs' case, including the revamped version of it – that the FDA claimed to be unfamiliar with PFS as an endpoint – is flatly untrue.

C. Plaintiffs' First Fallback Theory – That The FDA Was Unfamiliar With PFS And Thus Could Not Have Agreed To GPC's Use Of It – Is Both Illogical And Contradicted By Indisputable Facts

The first of Plaintiffs' two theories of the case is that GPC deliberately misled investors by representing, falsely, that the FDA had agreed to GPC's use of PFS as a primary endpoint in the SPARC trial. Pltfs. Opp. at 2. Plaintiffs' only basis for this assertion is that, according to Plaintiffs, the FDA told GPC that it had no prior experience with PFS and, thus, could not have agreed to its use in the SPARC trial. *Id.* at 1-3. This theory fails for at least three reasons.

First, Plaintiffs' reasoning is an obvious non-sequitur as it requires the Court to make an entirely unwarranted logic leap. Even if the PFS endpoint were new to the FDA, it does not follow that the FDA would not have agreed to its use in the SPARC trial. New and unacceptable are two different things, especially considering that medical and scientific inquiry is not static in nature, but instead necessarily evolves over time. Moreover, every endpoint the FDA now regards as acceptable was once new to it. The notion that the FDA would automatically refuse to accept an endpoint merely because it is in some way novel is fallacious and certainly not a sufficient foundation for an actionable securities fraud claim.

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[6] For example, in discussing a portion of the SPARC protocol that measured progression through the examination of bone scans by two independent radiologists, the FDA observed that the two reviewers frequently reached conflicting conclusions. FDA Briefing Document at 3, Garbutt Aff., Exh. 8. Evidently, this led the FDA to wonder whether this component of the SPARC trial's composite PFS measure was too subjective to provide reliable evidence of satraplatin's effect on PFS. *Id.*

Second, and far more important, Defendants have already thoroughly debunked the premise of this argument – *i.e.*, that the FDA was inexperienced with PFS as an endpoint in oncology drug trials. Plaintiffs' intransigence on this point in the face of the abundant incontestable evidence to the contrary is startling, but telling.

Finally, as noted, given the context of the FDA's expression of inexperience, the FDA was obviously referring only to GPC's composite criteria for measuring PFS for purposes of the SPARC trial. Accordingly, the FDA's comment in no way supports Plaintiffs' contention that GPC's representation that the FDA agreed to the use of the PFS endpoint was false.

D. Plaintiffs' Second Fallback Theory – That GPC Defrauded Investors By Failing To Disclose The FDA's Unfamiliarity With GPC's Composite Criteria For Measuring PFS – Is Equally Baseless

Although refusing to retreat from their indefensible position that the FDA lacked experience with PFS, Plaintiffs themselves eventually torpedo that theory by grudgingly acknowledging that the FDA may indeed have been referring only to the agency's inexperience with GPC's specific composite criteria for measuring PFS. Pltfs. Opp. at 12. Hence their need to offer yet another fallback theory of liability, which Plaintiffs articulate as follows:

> Defendants never stated that while the FDA approved the use of PFS as a primary endpoint in the abstract, it had not agreed, and was not familiar with, the manner in which GPC would attempt to demonstrate progression-free survival. In reporting positive results from the clinical trials, Defendants never stated that FDA approval was still at risk because the agency, which had already approved the PFS endpoint, raised specific concerns with the elements of that endpoint or the Company's methodology for demonstrating it.

Pltfs. Opp. at 12-13. Plaintiffs are, in other words, arguing that GPC's nondisclosure of the FDA's inexperience with GPC's specific composite PFS definition was fraudulent because it led investors to believe that the FDA's agreement to GPC's use of a PFS endpoint meant that approval was no longer "at risk."

Before turning to the many reasons why Plaintiffs' fraudulent omission case is specious, it should be noted that, embedded within it is an assertion of fact that does not appear in the Complaint but is instead drawn from thin air – namely, that the FDA "raised specific concerns with the elements of [GPC's composite endpoint] or the Company's methodology for demonstrating it." Pltfs. Opp. at 13. This attempt by Plaintiffs to salvage their facially deficient Complaint by amending it in their opposition brief is improper. In any event, such an amendment would not save Plaintiffs' case because their naked assertion that the FDA raised "concerns" about GPC's PFS definition is unsupported by any details about the nature of the concerns, who communicated them, or how and when they were expressed during the multi-year "development phase" of satraplatin. Moreover, if the "concerns" Plaintiffs have in mind are those set forth in the FDA's July 20, 2007 Briefing Document, the Complaint contains no facts from which one could infer that the FDA raised any of them with GPC at any time ***before*** it issued the Briefing Document.[7] Plaintiffs' reference to unspecified FDA "concerns" must therefore be disregarded for purposes of Defendants' motion to dismiss.

That leaves only one question: Did GPC's failure to disclose the FDA's professed unfamiliarity with GPC's specific PFS measure render its representation that the FDA had agreed to the PFS endpoint materially misleading? The answer no, for the following reasons.

First, as already noted, an FDA agreement that a demonstrated effect of satraplatin on PFS could lead to accelerated approval is completely different from an FDA agreement that the

[7] Asking the Court to infer from the concerns in a July 2007 Briefing Document that the FDA must have also raised them at some earlier time amounts to pleading fraud by hindsight, a practice the courts have routinely rejected. *See, e.g., Garber v. Legg Mason, Inc.*, 537 F. Supp. 2d 597, 615 (S.D.N.Y. 2008) ("the Second Circuit does not recognize 'fraud by hindsight.'"). *See also Noble Asset Mgmt. v. Allos Therapeutics*, No. CIVA-04CV-1030-RPM**,** 2005 WL 4161977, at *11 (D. Colo. Oct. 20, 2005) ("[t]he interpretation of the data from the [company's] clinical trials is a matter on which reasonable minds could differ . . . . The fact that the ODAC ultimately did not recommend approval does not mean that the defendants' statements about the results or design of the study were false. The plaintiff's characterization of the defendants' statements as misleading falls into the category of 'fraud by hindsight.'")

actual clinical trial results, including the means by which PFS was measured, do in fact constitute proof of such efficacy. It follows that the FDA's expression of inexperience with GPC's PFS measurement criteria does not in any way conflict with, or undermine the import of, the FDA's agreement that satraplatin, if proven to be effective based on the PFS endpoint, could well be granted accelerated approval.

Second, Plaintiffs' argument that the nondisclosure was material because it led investors to believe that approval was no longer "at risk" is also easily refuted. Pltfs. Opp. at 12-13. In reporting that the FDA had agreed to GPC's use of the PFS endpoint, GPC was not, as Plaintiffs would have the Court believe, representing that accelerated approval was thereby already assured, regardless of the outcome of FDA's analysis of the actual clinical trial data later presented to it. To the contrary, GPC explicitly warned its shareholders that the FDA's acceptance of PFS as an endpoint did ***not*** guarantee the FDA's ultimate acceptance of the validity of the SPARC trial data as proof of satraplatin's effect on PFS, and that the FDA might find the PFS results from the SPARC trial insufficient to establish a clinical benefit, and might also require an overall survival benefit. For example, in GPC's 2005 Form 20-F, it stated:

> the FDA may not grant an accelerated approval if it concludes that the progression-free survival data and available overall survival data do not demonstrate that satraplatin provides a meaningful therapeutic benefit to patients over existing treatments or that the data are otherwise inadequate to support the granting of an accelerated approval due to weaknesses, inconsistencies or differences in the data with respect to data subsets or subpopulations in the treatment group.

GPC's 2005 Form 20-F, at 5, Garbutt Aff., Exh. 1;[8] *see also id.* at 5 ("[t]he FDA will review the progression-free survival data together with available overall survival data in considering whether to grant such an approval"); *id*. at 6, 16, Supp. Garbutt Aff., Exh. 13 ("[a] successful 'End-of-Phase 2 meeting,' Special Protocol Assessment and a Scientific Advice letter, however, do not guarantee that satraplatin will receive regulatory approval," and the FDA may not approve the drug "[i]f the trial fails to demonstrate that satraplatin is safe or effective in FDA's risk benefit evaluation, or the results of the trial are not statistically convincing, internally consistent or clinically meaningful or are otherwise deemed inadequate by the FDA"). Thus, in view of the specific disclosures and warnings to the contrary, investors cannot reasonably have believed that approval of satraplatin would be assured if the SPARC trial yielded positive data on PFS. *See, e.g., Steinberg v. PRT Group, Inc.*, 88 F. Supp. 2d 294, 300 (S.D.N.Y. 2000) (Chin, J.) ("[u]nder the bespeaks caution doctrine, 'a misrepresentation or nondisclosure will be deemed immaterial if surrounded by cautionary language sufficiently specific to render reliance on the misrepresentation unreasonable"). The challenged statements are also projections about the likelihood of FDA approval, and, by reason of the same disclosures and warnings, fall under the Safe-Harbor rule of 15 U.S.C. §78u-5(c)(1). *See Noble*, 2005 WL 4161977, at *9.

Third, implicit in Plaintiffs' nondisclosure claim is the notion that a sponsor of an NDA must disclose to the public every comment, suggestion, reservation, or concern articulated by the FDA during the years it generally takes to obtain approval. That is not the law. Courts have

[8] Moreover, the Guidance Document, which is publicly available, notes, "[u]ltimately, of course, marketing approval depends not only on the design of clinical trials, but on *FDA review of the results and data* from all studies in the drug marketing application." Guidance Document at 13, Supp. Garbutt Aff., Exh. 12 (emphasis added); Draft Guidance Document at 17, Supp. Garbutt Aff., Exh. 11 (same). Thus, regardless of the methods that any trial uses to establish a PFS benefit in any type of cancer resulting from any particular drug, the FDA's Guidance Document informs the public that the FDA will carefully scrutinize even apparently positive PFS data to determine whether they actually establish a clinical benefit for the type of cancer under study, and thus whether the PFS data support approval.

rejected the proposition that a drug sponsor must provide "blow-by-blow" reports on even routine dealings with the FDA so as to ensure that shareholders are abreast of every utterance that may telegraph the FDA's thinking on some aspect of the approval process. For example, in *Noble Asset Management v. Allos Therapeutics*, the plaintiff alleged that the defendants' positive statements about the clinical trial results were misleading because the defendants "did not disclose that the FDA had voiced concerns to [the defendant] . . . about the [clinical trial's] subgroup analysis." 2005 WL 4161977 at *7. The court disagreed, stating that "[t]he fact that the FDA staff members raised questions did not impose a duty upon the defendants to revise their opinions about the drug's efficacy or to report to the public the substance of their conversations with the FDA." *Id.*

To the same effect is *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md. 1995), in which the court held that, "as a general proposition, [a defendant has] no duty to report its ongoing discussions with FDA during the review process." The court reasoned that:

> Continuous dialogue between the FDA and the proponent of a new drug is the essence of the product license application process. . . . Requiring ongoing disclosure of FDA's questions would not only be disruptive to the review process; it could easily result in misleading the public more than not reporting the questions.

Id. at 966. Therefore, even if the FDA's observation that it was inexperienced with GPC's specific composite PFS definition could fairly be characterized as an expression of "concern," GPC was under no obligation to disclose that concern, and its failure to do so did not mislead investors about the likely outcome of the satraplatin NDA.

Finally, Plaintiffs' nondisclosure argument unreasonably assumes that the FDA's inexperience with GPC's composite PFS endpoint raised serious doubts about satraplatin's approvability. Plaintiffs cite no FDA rule that disallows the use of criteria for measuring

efficacy that are novel. Indeed, every efficacy measure the FDA has ever accepted as proof of approvability was, at one point, new to the FDA. Moreover, innovations in medicine, science, and technology that offer new investigative techniques or otherwise enable clinical investigators to gather more robust and meaningful reliable clinical data necessarily do – and should – introduce novelty into clinical study design. As a consequence, notions about which efficacy criteria offer the strongest evidence of a drug's approvability necessarily evolve over time.

In fact, the FDA has affirmatively *advocated* the use of criteria for measuring PFS that have not been used in the past (criteria with which the FDA is, by definition, inexperienced). In its April 2005 draft of the Guidance Document, the FDA stated that "[i]n the future, it is important that other methods of progression assessment be evaluated as potential surrogate endpoints for regular approval." Draft Guidance Document at 11, Supp. Garbutt Aff., Exh. 11.

Against this backdrop, the novelty of GPC's composite endpoint could fairly be viewed as enhancing, rather than diminishing, the likelihood that satraplatin would be approved. As noted, GPC's composite endpoint was unfamiliar to the FDA at least in part because, rather than considering only one manifestation of the progression of HRPC, it went further by testing satraplatin's efficacy against several previously accepted measures of progression, which prompted one leading expert to describe it as a "rigorous" PFS definition that "set the standard for prostate cancer trials in the future." Pacific Growth Equities Analyst Report dated February 26, 2007 at 3, Garbutt Aff., Exh. 5.

Thus, even after abandoning the theory of liability pled in their Complaint and proffering two new fallback theories, Plaintiffs still have failed to allege a single false or misleading statement by GPC in support of their securities fraud claim. Plaintiffs' Complaint should therefore be dismissed in its entirety.

II. DEFENDANTS CAN BE LIABLE ONLY FOR STATEMENTS THEY MADE

Plaintiffs have still failed to establish a basis for imposing liability upon Defendants Seizinger or Scherer for statements that they did not make. Pltfs. Opp. at 17.[9] Although Plaintiffs rely upon the "group pleading" doctrine, they do not address this Court's decision in *Ellison v. American Image Motor Co., Inc.,* 36 F. Supp. 2d 628, 640-41 (S.D.N.Y. 1999), nor do they address Defendants' analysis under *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 128 S. Ct. 761 (2008). Furthermore, Plaintiffs ignore the reasoning that has led all of the Courts of Appeal that have addressed the issue to conclude that group pleading did not survive enactment of the PSLRA. Defs. Mem at 17-18. Defendants respectfully submit that this Court should reject group pleading.

III. THE COMPLAINT FAILS TO ADEQUATELY ALLEGE LOSS CAUSATION

Plaintiffs have not sufficiently alleged loss causation because the Complaint contains no allegations from which one could infer that there was a causal connection between the GPC stock price decline (following the FDA's July 2007 Briefing Document) and the alleged "fraud."

Plaintiffs concede that "there may have been reasons for the sharp decline in GPC's stock price in July 2007 in addition to the FDA committee's Briefing Document . . ." Pltfs. Opp. at 18; s*ee also id.* at 19 (Defendants "may be right that there were other causes in addition to those cited by Plaintiff that led to the rise and fall of GPC's stock price."). Plaintiffs' concession is unavoidable given that the document they contend revealed the "truth" contained ***four*** other issues that the FDA raised regarding GPC's application, any one of which could have been the

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[9] Plaintiffs now concede they are not asserting Section 10(b) claims against Defendants Maier or Meier-Ewert. Pltfs. Opp. at 17 n.36. Although Plaintiffs contend that group pleading is allowed in the "Second Circuit," Pltfs. Opp. at 16, Defendants are not aware of any Second Circuit decision holding that group pleading survived the PSLRA. Nor do cases within the Southern District of New York unanimously hold that group pleading survived. *See, e.g., In re Cross Media Mktg. Corp. Sec. Litig.*, 314 F. Supp. 2d 256, 262 (S.D.N.Y. 2004); *Bond Opportunity Fund v. Unilab Corp.*, 99 Civ. 11074 (JSM), 2003 WL 21058251, at *4 (S.D.N.Y. May 9, 2003), *aff'd*, 87 Fed. Appx. 772 (2d Cir. Feb. 10, 2004).

sole or partial cause of the stock price decline. Defs. Mem. at 21; FDA Briefing Document at 3-4, Garbutt Aff., Exh. 8 (identifying four other issues: (1) whether PFS could be reliably assessed in light of the rate of disagreement among radiology readers; (2) whether the assessment of pain progression was appropriate; (3) whether all patients should have had prior docetaxel treatment even though the SPARC trial was started prior to FDA's approval of docetaxel; and (4) whether FDA should wait for final overall survival analysis).

Moreover, under any fair reading of the ODAC Meeting Minutes, it is clear that the four other issues – and not any concern about the composite PFS definition – led to the decision that caused the drop in GPC's stock price. The Minutes state that "[d]ue to time constraints, [this PFS definition issue] was not addressed by the committee." *Id.* at 8-9.

The Second Circuit has held that, when information that allegedly revealed a fraud is included in a mix of other negative, non-fraudulent information that may have also caused a stock's price to decline, the plaintiff must do more than conclusorily assert that revelation of the fraud caused *some* of the price decline. As the Court explained in *Lentell v. Merrill Lynch & Co., Inc.*, 396 F.3d 161, 177 (2d Cir. 2005), a plaintiff must allege:

> (i) facts sufficient to support an inference that it was defendant's fraud – *rather than other salient factors* – that proximately caused plaintiff's loss; or (ii) facts sufficient to *apportion* the losses between the disclosed and concealed portions of the risk that ultimately destroyed an investment.

(emphasis added). Similarly, in *Lattanzio v. Deloitte & Touche LLP*, 476 F.3d 147, 158 (2d Cir. 2007), the court affirmed dismissal for failure to allege "facts to show that Deloitte's misstatements, [among statements made by other parties] that were much more consequential and numerous, were the proximate cause of the loss; nor have they alleged facts that would allow a factfinder to ascribe some rough proportion of the whole loss to Deloitte's misstatements."

This case is analogous to *In re Merrill Lynch & Co. Research Reports Sec. Litig.*, -- F. Supp. 2d --, No. 02 MDL 1484, 07 CIV 6677(JFK), 2008 WL 2019680 (S.D.N.Y. May 8, 2008). There, the plaintiff sought to avoid the holding in *Lentell* by claiming that he had identified one particular research report that caused the issuer's stock price to decline by revealing the company's liquidity problems, which had previously been concealed. *Id.* at *9-10. The court dismissed the complaint for, *inter alia*, the failure to allege loss causation because it did not "account for the fact that the [research] report contained other 'bad news,' apart from the concern about [the issuer's] cash position, that was likely to cause a drop in the company's share price." *Id.* at *14. Plaintiff's "attempt to plead loss causation fails because he has not alleged facts that lead to the inference that all, or even some, of his losses are due to the alleged fraud, rather than to intervening events and/or to the disclosure of other information." *Id.*

Plaintiffs in this case have failed to plead loss causation because the Complaint fails to allege any facts that would give rise to a reasonable inference that the question raised by the FDA about GPC's composite PFS definition, rather than any of the other four issues the FDA raised, accounted for the decision to delay action on GPC's request for accelerated approval and thus proximately caused the decline in GPC's stock price.

IV. THE COMPLAINT FAILS TO ALLEGE FACTS SUPPORTING A STRONG INFERENCE OF SCIENTER

A. There Is No Inconsistency Between The FDA's Purported Communications And GPC's Statements to Investors

Plaintiffs argue that, based upon the 2007 FDA Briefing Document, Defendants "knew that … the FDA had not agreed to GPC's use of PFS as a primary endpoint for the clinical trials (or, as Defendants claim, that the FDA had expressed its lack of experience with the tests Defendants intended to employ to demonstrate the effectiveness of satraplatin from a PFS perspective)." Pltfs. Opp. at 22. However, as Defendants have established, *supra* and in

Defendants' Memorandum, there is no support (in the Complaint's allegations or elsewhere) for Plaintiffs' argument that the statements were, in fact, fraudulent.[10]

Earlier this year, a court rejected nearly the same argument. That court refused to infer scienter simply because the company decided to present the FDA with a "new plan," finding that merely because the company was using a "new approach" did not mean that the defendants knew "the new approach [was] likely to fail." *Construction Laborers Pension Trust of Greater St. Louis v. Neurocrine Biosciences, Inc.*, No. 07CV1111-IEG-RBB, 2008 WL 2053733, at *5, *8 (S.D. Cal. May 13, 2008) (distinguishing cases, including *Amylin* — discussed below — where "the pharmaceutical company communicated with the FDA about the same problems which ultimately caused the FDA not to approve the drug").

In support of their argument that Defendants knew satraplatin would not be approved because they knew the FDA did not have prior experience with the composite PFS endpoint for the SPARC trial, Plaintiffs err in relying on *In re Amylin Pharms. Inc. Sec. Litig.*, No. 01-1455, 2003 U.S. Dist. LEXIS 7667, at *12-13 (S.D. Cal. May 1, 2003). Pltfs. Opp. at 22-23. That case is entirely distinguishable because *Amylin* involved allegations that a company knew that its diabetes drug would not be approved because the FDA had informed it that the study methodology was inherently flawed and therefore that "the current study data is not considered pivotal data for an NDA." 2003 U.S. Dist. LEXIS 7667 at *4. As noted in *Neurocrine*, the *Amylin* court found that the company "knew that the FDA had serious concerns about its study designs which could prevent the approval" of the drug. *Id.* at *12. Here, in contrast, the FDA had approved PFS as an endpoint for the SPARC trial, and there is *no allegation* supporting

[10] Plaintiffs' suggestion that Defendants hid facts that they should have disclosed is hollow given that GPC actually disclosed those facts. GPC did not provide warnings that "related only to the general risks that its satraplatin application might not be approved," Pltfs. Opp. at 15. Rather, Defendants specifically disclosed that the FDA would review overall survival data as part of the accelerated approval process and would require overall survival data for full approval. 2005 20-F at 5, Garbutt Aff., Exh. 1.

Plaintiffs' assertion that the FDA voiced any "concerns" to Defendants regarding GPC's plan for measuring satraplatin's efficacy against PFS, let alone any indication that the FDA pointed to a conceptual flaw in the SPARC trial's design. *Teamsters Local 445 Freight Division Pension Fund v. Dynex Capital, Inc.,* 531 F.3d 190, 196 (2d Cir. 2008) (scienter insufficiently alleged where plaintiffs "have not specifically identified any reports or statements … that would have demonstrated the falsity of the allegedly misleading statements"). Moreover, the fact that the FDA accepted the NDA for priority review demonstrates that the FDA did not consider the trial design to be fundamentally flawed.

In trying to bring this case within the ambit of *Amylin*, Plaintiffs again inexcusably distort the FDA's statement that it lacked "prior experience" with PFS by suggesting that, in doing so, the FDA had conveyed "specific concerns" about the "methodology" of the SPARC trial. Pltfs. Opp. at 12-13. As noted above, there is no support for that inferential leap, thus precluding a claim that Defendants acted with scienter. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2511 (2007) (due to PSLRA's specificity requirement, "ambiguities count against inferring scienter").[11]

[11] Plaintiffs miss the mark with their suggestion that they need not establish that the individual Defendants had actual knowledge of the FDA's purported communications because officers and directors are deemed to have knowledge of the company's "core business." Pltfs. Opp. at 23. In *Neurocrine*, 2008 WL 2053733, at *8, the court determined that, absent specific details about when and to whom concerns about the sufficiency of a new drug's FDA approval application were raised, allegations concerning the significance of the drug to a small biopharmaceutical company's business provided "weak" support for an inference of the corporate officers' scienter. Similarly, here, the mere fact that the approval of satraplatin was important to GPC does not suggest that each of its officers and directors must have known anything, let alone everything, the FDA communicated to any representative of GPC. Plaintiffs' cases are not to the contrary. *See, e.g., In re Atlas Air Worldwide Holdings, Inc. Sec. Litig.*, 324 F. Supp. 2d 474, 489 (S.D.N.Y. 2004) (imputing knowledge of financial statements in documents officers had signed); *In re Cell Pathways Inc. Sec. Litig.,* No. 99-752, 2000 U.S. Dist. LEXIS 8584, at *22-23 (E.D. Pa. June 20, 2000) (allegations that were "substantially more extensive" than defendants' "mere status within the Company"); *In re Viropharma, Inc. Sec. Litig.*, No. Civ. A. 02-1627, 2003 WL 1824914, at *9 (E.D. Pa. Apr. 7, 2003) (inferring scienter because defendants had access to certain reports and test results).

B. Plaintiffs Have Failed To Allege Facts Suggesting A Motive To Defraud

Plaintiffs have also failed to show that any of the Defendants had a motive to defraud investors. They have abandoned their erroneous assertion that the general motive of raising capital suggests scienter. *See, e.g., Dynex,* 531 F.3d at 196. Moreover, Plaintiffs do not deny that the motive to obtain FDA approval before the patent expired was common to all GPC's competitors, and thus not indicative of scienter. Plaintiffs also fundamentally misunderstand Defendants' argument about the expiration of the patent. As Defendants established in their principal brief, if satraplatin were approved, GPC would have five years of regulatory exclusivity *from the date of approval*, even if the original patent were to expire before the approval was obtained. Defs. Mem. at 26. Plaintiffs provide no contrary authority.

Nor have Plaintiffs shown any motive by reason of insider trading. Plaintiffs do not contest Defendants' arguments that sales do not support scienter unless they are unusual and that Plaintiffs are required to put Defendants' sales in context to allege scienter. Defs. Mem at 29-30. However, Plaintiffs do not allege any of the required information, and ignore the fact that the individual stock sales were not timed to maximize personal benefit. Defs. Mem. at 30. Although Plaintiffs note that sales were made in time periods that followed certain announcements, the fact that certain sales occurred close to some announcements does not show scienter, as insiders are often limited to certain small trading windows. *In re Party City Sec. Litig.*, 147 F. Supp. 2d 282, 312 (D.N.J. 2001) (discussing trading windows); *see also In re Tyco Int'l, Ltd. Sec. Litig.*, 185 F. Supp. 2d 102, 112, n.6 (D.N.H. 2002) (same).

Plaintiffs' arguments also fail to avoid the effect of Defendants' 10b5-1 trading plans. They claim that when Defendants entered into the plans they already knew that the FDA had no "experience" with PFS. Pltfs. Opp. at 29-30. However, as discussed above, Plaintiffs have failed to allege that the FDA told any of the Defendants anything relating to its experience or that

otherwise led Defendants to believe satraplatin would not be approved. Accordingly, there is no basis to infer that the individual Defendants did not enter into the 10b5-1 plans in good faith.

C. Any Inference Of Scienter Is Outweighed By Inferences Of Non-Fraudulent Motives

Plaintiffs' allegations, viewed collectively and in context, actually support inferences of non-fraudulent motives that are "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *See Tellabs*, 127 S. Ct. at 2510. Their allegations establish that legitimate reasons existed for optimism about satraplatin's chances for approval, which decidedly outweigh any notion that Defendants did not believe in satraplatin's chances for approval. Plaintiffs do not deny that the drug was intended to fill a critical and unmet need, treating prostate cancer patients whose disease had progressed despite other treatment, and were out of options. Plaintiffs do not deny that the FDA recognized the importance of this when it granted satraplatin fast-track approval. Pltfs. Opp. at 4. Plaintiffs do not deny that each of the elements used to measure PFS had been used in prior studies. Deutsche Bank Analyst Report, dated July 22, 2007 at 4, Garbutt Aff., Exh. 7. Indeed, one of the same analyst reports cited by Plaintiffs states that leading experts opined "that the design of the PFS endpoint [in the SPARC trial], being a composite of tumor and pain progression, as well as the conduct of centralized review, are rigorous and set the standard for prostate cancer trials in the future." *See* Pacific Growth Equities Analyst Report, dated February 26, 2007 at 3, Garbutt Aff., Exh. 5. GPC expended millions of dollars from 2003 through 2006 to try to obtain the FDA's approval. 2005 20-F at 57, 2006 20-F at 59, Supp. Garbutt Aff., Exhs. 13 & 14. Significantly, *Plaintiffs do not even dispute that the SPARC trial yielded highly statistically significant results which showed that satraplatin provided a benefit in progression-free survival and was "extremely effective" in slowing the progress of prostate cancer.* Cmp. ¶94.

Although the FDA and ODAC ultimately raised questions about whether the SPARC trial's results could be viewed as reliably establishing a PFS benefit, their questions related to issues that arose *after the* study began. *See, e.g.,* FDA Briefing Document at 3-4 (*e.g.,* noting that about one-half of the study participants received prior treatment with another drug (docetaxel), which the FDA had not approved until after the SPARC trial had begun; and questioning results on radiographic progression because the radiologists who reviewed the participants' bone scans had reached inconsistent conclusions), Garbutt Aff., Exh. 8. Plaintiffs do not suggest, for example, that Defendants knew before the trial began that radiologists would disagree about participants' bone scans. Nor do Plaintiffs allege any facts showing Defendants knew the FDA would raise such issues, much less that they might be an obstacle to approval. Indeed, even after the FDA raised these questions in 2007, one analyst concluded "we still see a realistic chance for a positive vote on accelerated approval." Garbutt Aff., Exh. 7 at 1.

In short, Plaintiffs have failed to plead a theory of scienter that is cogent and at least as compelling as any opposing inference of non-fraudulent intent. While the Complaint tries to allege that the individual Defendants misled investors simply in order to sell their stock at high prices, Plaintiffs "have not alleged anything to negate the idea that defendants were attempting to develop a drug they thought beneficial and were so describing it to the public." *In re AstraZeneca Sec. Litig.*, No. 05 civ 2688 (TPG), __ F. Supp. 2d __, 2008 WL 2332325, *18 (S.D.N.Y. June 3, 2008) (granting motion to dismiss). "[P]eople in charge of an enterprise are not required to take a gloomy, fearful, or defeatist view of the future; … they can be expected to be confident about their stewardship and the prospects of the business they manage." *Id.* at *17 (quoting *Shields v. City-Trust Bancorp*, 25 F.3d 1124, 1129-30 (2d Cir. 1994)).

V. THE CONTROL PERSON AND SECTION 20A CLAIMS FAIL AS A MATTER OF LAW

Plaintiffs erroneously state that Defendants challenge only the first element of their control person claims (an underlying violation), Pltfs. Opp. at 34, and ignore Defendants' arguments that they have failed to plead culpable participation by the individual Defendants. Defs. Mem. at 31. Thus, the claim under Section 20(a) should be dismissed because Plaintiffs have not stated a valid claim under Section 10(b), nor have they alleged culpable participation.

Plaintiffs also make no effort to sustain their Section 20A claims for any of the challenged sales by Defendants, other than the sales in June and July 2007. Pltfs. Opp. at 31-32. Accordingly, the Section 20A claims for all other sales, Cmp. ¶145, should be dismissed.

Plaintiffs' only argument in support of what remains of their Section 20A claims is that courts in this Circuit have allowed such claims to proceed even when the trades were a few days apart. Pltfs. Opp. at 31-32. However, there is no controlling authority supporting Plaintiffs' position. This Court should adopt the more well-reasoned interpretation that requires a strict same-day limit for the contemporaneous requirement; this is the only interpretation that ensures that plaintiff and defendant could have actually traded with one another. Defs. Mem. at 32-33.

As to the two trades (a purchase by Plaintiff and a sale by Defendant) that actually occurred on the same day (June 12, 2007), Plaintiffs do not address Defendants' argument that the plain language of Section 20A requires that the security purchase be of "securities of the same class" as the allegedly improper sale. 15 U.S.C. §78t-1(a); *see also In re Enron Corp. Sec. Deriv. & ERISA Litig.*, 258 F. Supp. 2d 576, 639 n.66 (S.D. Tex. 2003) (dismissing Section 20A claim where shares in purchase and sale were not "securities of the same class"). This requirement is obviously not met here with respect to the June 12th transaction, given that Defendant Maier sold Ordinary Shares on the *Frankfurt Stock Exchange* but Plaintiff Chua

purchased American Depositary Receipts on the *NASDAQ*. *Compare* Cmp.¶99 *with* Cmp. Exh. B (reflecting respectively, Maier's sale in euros and Chua's purchase in dollars); Cmp. ¶31. Plaintiffs also ignore the fact that, regardless of the time limit used to define a contemporaneous trade, the requirement of contemporaneity serves only "as a proxy for the traditional requirement of contractual privity between plaintiffs and defendants." *In re AST Research Sec. Litig.*, 887 F. Supp. 231, 233 (C.D. Cal. 1995). Because the shares at issue here were sold and purchased in different formats denominated in different currencies and on different exchanges, there is no possibility of contractual privity and thus of a contemporaneous trade.

Even if this Court were to consider sales and purchases within a few days of one another as "contemporaneous," Plaintiffs have not cited any case law that allows them to maintain a Section 20A claim based upon purchases that occurred *before* Defendants' sales. Accordingly, Plaintiff Axxion's June 11, 2007 purchase cannot form the basis of any Section 20A claim because it was before any of Defendants' sales. Similarly, Plaintiff Chua's purchase on June 12, 2007 cannot form the basis of a Section 20A claim based on sales by Defendants Maier, Meier-Ewert and Seizinger on June 15, 2007, June 18, 2007 and June 19, 2007. Furthermore, Plaintiffs have not provided any reason why a *ten* day window is "contemporaneous" (*double* the time allowed in *In re Oxford Health Plans, Inc. Sec. Litig.*, 187 F.R.D. 133, 144 (S.D.N.Y. 1999)). Therefore, Plaintiff Axxion's purchase on July 23, 2007 cannot be considered contemporaneous with Defendant Scherer's sales on July 13, 2007.

Accordingly, even using Plaintiffs' laxer interpretation, the only sale which is a potentially "contemporaneous" transaction of securities of the same class is Defendant Seizinger's sale on July 19, 2007, which was four days before Plaintiff Axxion's purchase on

July 23, 2007. As noted above, this interpretation of "contemporaneous" does not maintain the proxy of contractual privity, and therefore the Section 20A claims fail as a matter of law.

VI. THE COURT SHOULD DENY PLAINTIFFS' REQUEST TO AMEND

Plaintiffs request leave to amend. However, they do not explain how they would cure the Complaint's inherent deficiencies. Plaintiffs will never be able to adequately allege, for example: what the FDA supposedly communicated to GPC that made GPC's statements false and misleading; when, how and to whom those supposed communications were made; and that the purported corrective disclosure, rather than a number of far more likely factors, actually caused the decline in GPC's stock price. The Court should deny leave to amend because amendment would be futile. *See Oneida Indian Nation of N.Y. v. City of Sherrill*, 337 F.3d 139, 168 (2d Cir. 2003). This Court has denied securities fraud plaintiffs leave to amend where the pleading deficiencies "were inherent in their claims." *See, e.g.*, *Arduini/Messina Partnership v. National Med. Fin. Servs. Corp.,* 74 F. Supp. 2d 352, 363 (S.D.N.Y. 1999) (Chin, J.).

CONCLUSION

For all the reasons set forth above and in Defendants' Memorandum, Defendants' motion to dismiss should be granted in its entirety.

Dated: New York, New York
August 8, 2008

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TO:

All Counsel of Record Via ECF or U.S. Mail

CERTIFICATE OF SERVICE

I, Namita E. Mani, an attorney duly admitted to practice before this Court and the courts of the State of New York, hereby certify that on August 8, 2008, I caused a copy of the following document to be served upon all counsel of record via ECF or U.S. Mail in accordance with the Local Rules of the Southern District of New York: Reply to Opposition to Defendants' Motion to Dismiss Plaintiffs' Consolidated Class Action Complaint.

Dated: August 8, 2008
New York, New York

/s/
Namita E. Mani